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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,408

Applicant(s)

CALDWELL ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response and affidavit under 37 C.F.R. 1.132, all received on 26 April 2004.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-5 and 19-27 under 35 U.S.C. 112, second paragraph is hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-18 and 24-28 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Biedermann *et al.* is hereby withdrawn.

The rejection of Claims 19-23 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Biedermann *et al.* and Shudo *et al.* is hereby withdrawn.

The rejection of Claims 1-18 and 24-28 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards and Biedermann *et al.* is maintained.

The rejection of Claims 19-23 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards, Biedermann *et al.*, and Shudo *et al.* is maintained.

Response to Arguments

Applicant's arguments filed 26 April 2004 have been fully considered but they are not persuasive. The examiner has considered the affidavit submitted under 37 C.F.R. 1.132, but it is not considered to be persuasive. Neither the three premises stated by the applicant, nor the statement that it would "not at all be certain that a sufficient amount of a given active agent would penetrate would penetrate deeply enough to reach" a target site are supported by any showing of evidence.

Since it is inappropriate for the examiner to rely on basic knowledge or common sense in applying the disclosure of the prior art against the claims, the examiner must instead look to the teachings of the prior art to find specific guidance for application against the instant claims. In this case, the Biedermann *et al.* patent is used merely to show that diclofenac and indomethacin are known in the art as acetic acid derivatives, rather than have the examiner merely proclaim that they are such without evidentiary support. In contrast, the Edwards patent is used to show a broad concept well known in the art. It is not used to show the application of a particular composition or active agent. Rather, it is used to point out that is well known in the prior art to apply a topical or transdermal pharmaceutical formulation at the site that is proximal to the source of pain, a disclosure that reflects the common sense approach that the prior art takes in applying topical and transdermal pharmaceutical formulations.

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The Petrus patent discloses the treatment of musculoskeletal disorders, a genus that certainly encompasses carpal tunnel syndrome. As the prior art discloses compositions that read on those used in the methods and kits claimed by the prior art, comprising the same ingredients and active agents, for use in conditions that encompass the one recited in the instant claims, it is the position of the examiner that the instant claims are obvious in view of the prior art. The Petrus patent discloses compositions that treat musculoskeletal disorders, while the Edwards patent discloses methods that are exemplary of those by which one of ordinary skill in the art would broadly apply any sort of topical or transdermal composition, proximal to the site of pain. This is not merely "obvious to try" as the applicant alleges. This is considered by the examiner to be sufficient guidance with which one of ordinary skill in the art can accomplish the same methods claimed by the applicant with a reasonable expectation of success. All pending claims remain rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600